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EXAMINER

TREYGER, ILYA Y

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MAIL DATE

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09/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,945	Applicant(s) AXELSSON ET AL.	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 45-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/22/2010 has been entered.
2. Claims 1-4, 6, 8-10, 17-19, 21, 23-29, 31 and 32 are amended.
3. Claims 36-44 are canceled.
4. Claims 45-72 are new.

Election/Restrictions

5. Newly submitted claims 45-72 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
 - I. Claims 1-35, drawn to a package and method for use in a peritoneal dialysis treatment, classified in class 604, subclass 403.
 - II. Claims 45-46, drawn to a package for use in a peritoneal dialysis treatment, classified in class 604, subclass 19.
 - III. Claims 47-71, drawn to a package for use in a peritoneal dialysis treatment, classified in class 604, subclass 29.
 - III. Claim 72, drawn to a method for manufacturing a package, classified in class 604, subclass 28.

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The inventions are distinct, each from the other because of the following reasons:

6. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the invention II does not require the first tubular line element extending in a first curved shape and the second tubular line element extending in a second curved shape. The subcombination has separate utility such as use in a peritoneal dialysis treatment.

7. Inventions III and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the invention III does not require the first tubular line element extending in a first curved shape and the second tubular line element extending in a second curved shape. The subcombination has separate utility such as use in a peritoneal dialysis treatment.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or

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divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

8. Inventions IV and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make a package, wherein the holding member comprises first and second recesses.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45-72 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

9. Claims 1-35 of are examined on the merits.

Response to Arguments

10. Applicant's arguments filed 02/04/2009 have been fully considered but they are not persuasive:

11. With regards to claim 1, Applicants argue that the combination of Dadson and Lee does not disclose the claimed invention because the combination of references does not disclose “a holding member configured to engage portions of the first and second tubular line elements, wherein the first tubular line element extends in a first curved shape from a first connector at an outer periphery of the first curved shape to the junction; wherein the second tubular line element

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extends in a second curved shape from a second connector at an outer periphery of the second curved shape to the junction; and - wherein the junction is disposed at an inner periphery of the first curved shape and an inner periphery of the second curved shape, such that no part of the line set extends across another part of the line set”, as recited in the amendment made to claim 1.

However, Lee teaches that it is known to use a clip for orderly arrangement of flexible lines that is a holding member connected to both first A and second B tubular elements. Since the clip of Lee defines the disposition of the tube elements within the same plane, and since the tubing of Dadson is formed from the flexible material (col. 4, line 10) the clip is fully capable of being arranged to organize the line set such that the first tubular line element extends in a first curved shape from a first connector at an outer periphery of the first curved shape to the junction; the second tubular line element extends in a second curved shape from a second connector at an outer periphery of the second curved shape to the junction; and wherein the junction is disposed at an inner periphery of the first curved shape and an inner periphery of the second curved shape, such that no part of the line set extends across another part of the line set (See Figs. 7-10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode.

12. With respect to claim 27, Applicant's arguments are substantially identical to arguments discussed above.

13. With respect to new claims 45-72, claims are directed to an invention that is independent or distinct from the invention originally claimed (see explanation above). Since applicant has

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received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45-72 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-4, 6-12, 18, 19, 21-26, 27, 19, 31, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885).

16. In Re claim 1, Dadson discloses a device for use in a peritoneal dialysis treatment (Abstract, line 1), wherein the package (Col. 5, line 61) includes:

a line set which comprising a first tubular line element 54 (fig. 1), a second tubular line element 52 (fig. 1), and an element 3 (fig. 1) that is a junction connected between the first and second tubular line elements.

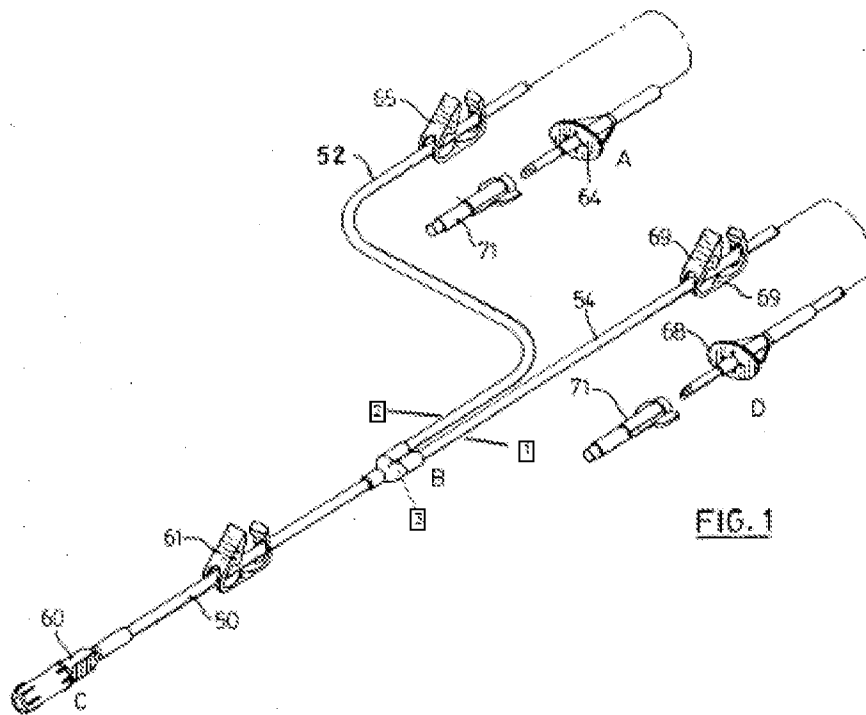
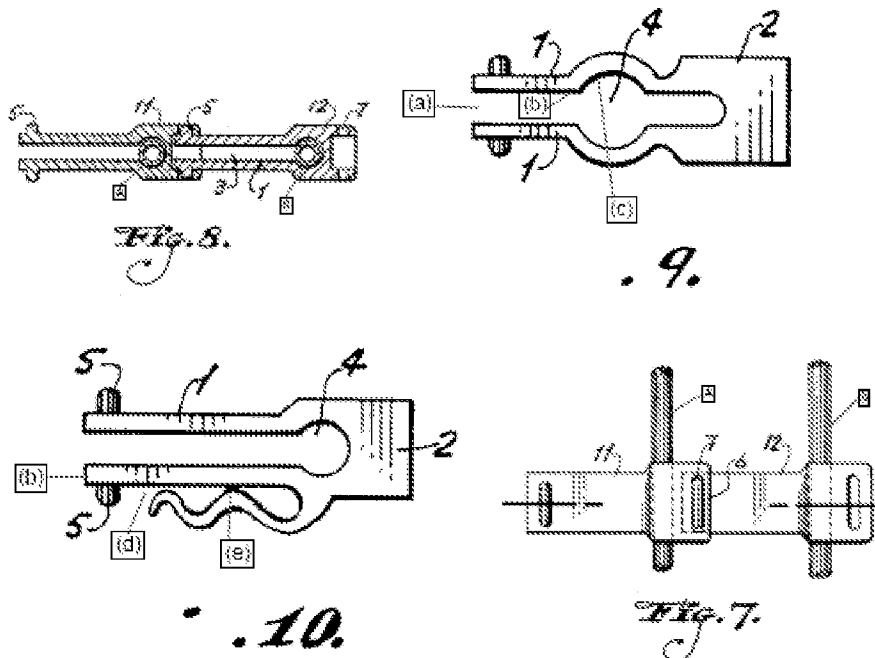


FIG. 1

Dadson does not expressly disclose the holding member configured to engage portions of the first and second tubular line elements.

Lee teaches that it is known to use a clip for orderly arrangement of flexible lines that is a holding member connected to both first A and second B tubular elements. Since the clip of Lee defines the disposition of the tube elements within the same plane, and since the tubing of Dadson is formed from the flexible material (col. 4, line 10) the clip is fully capable of being arranged to organize the line set such that the first tubular line element extends in a first curved shape from a first connector at an outer periphery of the first curved shape to the junction; the second tubular line element extends in a second curved shape from a second connector at an outer periphery of the second curved shape to the junction; and wherein the junction is disposed at an inner periphery of the first curved shape and an inner periphery of the second curved shape, such that no part of the line set extends across another part of the line set (See Figs. 7-10).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode.

17. In Re claim 2, Dadson discloses the claimed invention discussed above, but does not disclose the holding member is arranged to organize the whole line set at substantially the same planar level.

Lee teaches that it is known to make the holding member arranged to organize the whole line set fully capable of being non-sterile at substantially the same planar level (See Figs. 7-10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide a set being portable.

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18. In Re claim 3, Dadson discloses the claimed invention discussed above, but does not disclose the holding member arranged to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements.

Lee teaches that it is known to make the holding member fully capable of being arranged to organize the line set fully capable of being non-sterile such that no part of the first and second tubular line elements is in contact with another part of the first and second tubular line elements (See Figs. 8, 9, and 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the holding member arranged to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, as taught by Lee because such modification would prevent tubing from the mechanical damage during the storing the package.

19. In Re claim 4, since the tubing of Dadson is formed from the flexible material (col. 4, line 10), Dadson discloses the line set fully capable of being arranged so as the first curved shape is a first spiral, the second curved shape is a second spiral that is substantially coaxial with the first spira, and the junction is disposed at inner peripheries of the firs and second spirals.

20. In Re claim 6, Dadson discloses the claimed invention discussed above, but does not disclose the holding member configured to hold at least one portion of the first tubular line element in a predetermined position in relation to a portion of the second tubular line element.

Lee teaches using the holding member configured to hold at least one portion of the first tubular line element A in a predetermined position in relation to a portion of the second tubular line element B fully capable of being non-sterile (See Figs. 7 and 8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the holding member, as taught by Lee in order to prevent unpredictable moving of the tubing elements.

21. In Re claim 7, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means comprising the holding member arranged to perform said holding in a detachable manner.

Lee teaches the organizing means comprising the holding member performing the holding in a detachable manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means comprising the holder arranged to organize the line set in a detachable manner, as taught by Lee in order to simplify operation the device.

22. In Re claim 8, Dadson discloses the claimed invention discussed above, but does not disclose holding member comprising a first elongated recess, restricted by at least one resilient jaw-shaped member, said resilient jaw-shaped member being provided with at least one concavity for holding detachable said portion of the first tubular line element.

Lee teaches the organizing means comprising the holding member further comprising a first elongated recess (a), restricted by the resilient (Col. 3, ln. 47) jaw-shaped member (b) being provided with the concavity (c) for holding detachable the portion of the tubular member (See Fig. 9) fully capable of being non-sterile.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson with the holding member comprising a

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first elongated recess, restricted by the resilient jaw-shaped member being provided with the concavity for holding detachable the portion of the tubular member, as taught by Lee in order to improve the reliability of the holding the tubular element by the holding member.

23. In Re claim 9, Dadson discloses the claimed invention discussed above, as applied to claim 6 above, but does not disclose the organizing means wherein the holding member is configured to hold at least one portion of the first tubular line element and the at least one portion of the second tubular line element, said at least one portion of the first tubular line element and said at least one portion of the second tubular line element being configured in a predetermined position in relation to each other, such that the first and second tubular line elements have a substantially parallel extension in the vicinity of the holding member.

Lee teaches the organizing means wherein the holding member is configured to hold at least one portion of the first tubular line element A and a portion of the second tubular line element B, said one portion of the first tubular line element and said one portion of the second tubular line element being configured in a predetermined position in relation to each other, such that the first and second tubular line elements fully capable of being non-sterile have a substantially parallel extension in the vicinity of the holding member (See Fig. 7).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of holding member configured to hold at least one portion of the first tubular line element and the at least one portion of the second tubular line element, said at least one portion of the first tubular line element and said at least one portion of the second tubular line element being configured in a predetermined position in relation to each other, such that the

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first and second tubular line elements have a substantially parallel extension in the vicinity of the holding member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide device with the type of holding member that is known to be suitable for holding tubular elements in a predetermined position substantially parallel to each other.

24. In Re claim 10, Dadson discloses the claimed invention discussed above, as applied to claim 7, but does not disclose the holding member is configured to be connected to a second connector, said second connector being mounted to an end of the second tubular line element.

Lee teaches the holding member being is fully capable to be connected to a connector being mounted to an end of the second tubular line element fully capable of being non-sterile, since the organizing means can comprise the unlimited quantity of clips (holding members) comprising the concavity (c) for holding detachable the portion of the tubular member (See Figs. 7-10).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of holding member configured to hold fixedly a connector being mounted to an end of the tubular line element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide device with the type of holding member that is known to be suitable for holding fixedly a connector being mounted to an end of the tubular line element.

25. In Re claim 11, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means wherein the holding member comprises a hole extending through the holding member for receiving said connector.

Lee teaches the organizing means wherein the holding member comprises a pocket 4, which is a variation of the hole, and fully capable of receiving the connector mounted to the end of the tubular line element (See Figs. 8-10).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of the holding member comprising the hole for receiving the connector mounted to the end of the tubular line element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide the device with the type of holding member that is known to be suitable for holding the connector mounted to the end of the butulare line element.

26. In Re claim 12, Dadson discloses the line set comprising a drain bag, and the line set, fully capable of being non-sterile, is connected to the drain bag (See Col. 6, ln. 14).

27. In Re claim 18, Dadson discloses the package wherein the package comprises a drain bag and the line set, fully capable of being non-sterile, is connected to the drain bag via connector 68 positioned at an outer periphery of the line set (See Col. 6, ln. 7-9; Fig. 1).

28. In Re claim 19, Dadson discloses the package wherein the package comprises a solution bag and the line set, fully capable of being non-sterile, is connected to the solution bag (Col. 6, ln. 60, 61; Col. 7, ln. 16-18).

29. In Re claim 21, Dadson discloses the package wherein the line set is connected to the solution bag via connector 64 positioned at an outer periphery of the line set (See Col. 6, ln. 7-9; Fig. 1).

30. In Re claim 22, Dadson discloses the package wherein the solution bag is filled with a dialysate solution (Col. 6, ln. 60, 61).

31. In Re claim 23, Dadson discloses the package wherein the line set, fully capable of being non-sterile, comprises a third connector 60 connectable to a patient connector (See Col. 6, ln. 3-5; Fig. 1).

32. In Re claim 24, Dadson discloses the package wherein the third connector 60 is configured in a space at an inner periphery of the line set (See Fig. 1) fully capable of being non-sterile.

33. In Re claim 25, Dadson discloses the package wherein the line set comprises a component in the form of at least one flow organizer 65, 68 (Fig. 1) fully capable of being arranged to provide a space sufficient for the flow organizer such that the flow organizer does not load on any part of the first and second tubular line elements.

34. In Re claim 26, Dadson discloses the package wherein the package comprises a wrapping for encasing the line set (Col. 5, ln. 61, 62) since in accordance with the definition the package is “a wrapped or boxed object” (See The American Heritage® Dictionary of the English Language, Fourth Edition), what reads on comprises a wrapping.

35. In Re claim 27, Dadson discloses a method for manufacturing of a package for use in a peritoneal dialysis treatment (Abstract, line 1), wherein the package (Col. 5, line 61) includes a drain bag (col. 3, line 5), a line set which comprises a first tubular line element 54 fully capable

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of being non-sterile, a second tubular line element 52, an element 3 (fig. 1) that is a junction connected between the first and second tubular line elements, and a third tubular element 50 (fig. 1) connected between the junction and a patient connector, wherein the package is configured to substantially eliminate the risk of damage to the package or line set during sterilization, since the line set has been disclosed as supplied in sterile condition in a single PD package (Col. 5, lines 64, 65).

Dadson does not expressly disclose the organizing means connected to both first and second tubular elements and arranged to organize the line set such that no part of the line set extends across another part of the line set.

Lee teaches that it is known to use a clip for orderly arrangement of flexible lines that is a holding member fully capable of being connected to both first A and second B tubular elements. Since the clip of Lee defines the disposition of the tube elements within the same plane (See Figs. 7-10), the step of organizing the line set such that no part of the line set extends across another part of the line set and fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set is disclosed (See Figs. 7-10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson with the step of positioning of the line set and fixing of the holding member are configured to substantially eliminate damage to the package or line set by retaining the patient connector at an inner periphery of the line set and preventing any part of the line set from extending across another part of the line set, as taught by Lee because such modification would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode.

36. In Re claim 29, Dadson discloses the claimed invention discussed above, but does not expressly disclose the method characterized by the step of organizing the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements.

Lee teaches that it is known to use the organizing means capable to organize the line set, fully capable of being non-sterile, such that no part of the tubular line elements, fully capable of being non-sterile, is in contact with another part of the tubular line elements (See Figs. 8, 9, and 10), fully capable of being non-sterile.

Since the organizing means capable to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson with the step of organizing the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, as taught by Lee because such modification would prevent tubing from the mechanical damage during the storing the package.

37. In Re claim 31, Dadson discloses the claimed invention discussed above, but does not expressly disclose the method including the step of organizing the line set by means of a holding member being configured to hold at least one portion of the first tubular line element in a predetermined position, in relation to a portion of the second tubular line element.

Lee teaches the organizing means comprising the holding member configured to hold at least one portion of the first tubular line element A, fully capable of being non-sterile, in a predetermined position in relation to a portion of the second tubular line element B (See Figs. 7 and 8), fully capable of being non-sterile.

Since the organizing means capable to hold one portion of the tubular line element in a predetermined position in relation to another tubular line element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson with the step of organizing the line set by means of a holding member being configured to hold at least one portion of the first tubular line element in a predetermined position, in relation to a portion of the second tubular line element, as taught by Lee in order to prevent unpredictable moving of the tubing elements.

38. In Re claim 34, Dadson discloses the package wherein the package comprises a wrapping for encasing the line set (Col. 5, ln.61, 62), since in accordance with the definition the package is “a wrapped or boxed object” (See The American Heritage® Dictionary of the English Language, Fourth Edition), what reads on comprises a wrapping.

Since the package comprising the wrapping disclosed as provided, it means the step of providing the package with a wrapping has been disclosed.

39. Claims 5, 13, 15-17, 20, 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885) and further in view of Keilman (US 5,820,582).

40. In Re claim 5, Dadson in view of Lee disclose the claimed invention, as applied to claim 1 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein at least one tubular lane element is pre-shaped to extend along a desired path.

41. In Re claim 13, Dadson in view of Lee disclose the claimed invention, as applied to claim 1 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the first and second tubular line elements, are manufactured of PVC.

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Keilman teaches the system used for a peritoneal dialysis procedure (See Abstract, ln. 4, 5), wherein tubular line elements, fully capable of being non-sterile, are manufactured of PVC (See Col. 6, ln. 30-32).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of tubing for dialysis procedure made of PVC. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the PVC tubing of Keilman to the device of Dadson/ Lee in order to provide device with the tubing made of material that is known to be suitable for tubing set used for dialysis procedure.

42. In Re claim 15, Dadson in view of Lee disclose the claimed invention, as applied to claim 12 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is foldable to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag.

Keilman teaches the drain bag constructed of flexible plastic material (Col. 2, ln. 19, 20) and, consequently, fully capable of being folded in the claimed manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the flexible bag foldable to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag, as taught by Keilman in order to make the package portable.

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43. In Re claims 16 and 17, Dadson in view of Lee and further in view of Keilman disclose the claimed invention, , but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the holding member is arranged to detachably engage one of said first and second folded parts of the drain bag, and wherein the holding member comprises a second recess restricted by at least one resilient jaw-shaped member, said jaw-shaped member is provided with at least one protruding member for engaging detachably the edge area.

Lee teaches the holding member comprising the recess (d) restricted by the resilient jaw-shaped member (b), and protruding member (e) (See Fig. 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee / Keilman with the holding member, as taught by Keilman, since Keilman discloses substantially the same structure, as that claimed by applicant, the structure is fully capable of performing the claimed function of the holding member being arranged to detachably engage the folded part of the drain bag.

44. In Re claim 20, Dadson in view of Lee disclose the claimed invention, as applied to claim 12 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is applied on the solution bag.

Keilman teaches the system, wherein the drain bag is applied on the solution bag (See Col. 2, ln. 3, 10-13; Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the drain bag is applied on the solution bag, as taught by Keilman in order to form the package is such a manner to substantially reduce packaging size requirements and to simplify the packaging procedure.

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45. In Re claim 30, Dadson in view of Lee disclose the claimed invention, as applied to claim 27 above, but do not expressly disclose the method for use in a peritoneal dialysis treatment, including the step of organizing the line set in a spiral shaped state.

Keilman teaches the line set, fully capable of being non-sterile, provided in a spiral shaped state (See Fig. 1).

Since the line set organized in a spiral shaped state has been disclosed as provided, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson/ Lee with the step of organizing the line set in a spiral shaped state, as taught by Keilman because such modification would provide the compact packaging of the line set.

46. In Re claim 32, Dadson in view of Lee disclose the claimed invention, as applied to claim 27 above, but do not expressly disclose the method, the steps of folding the drain bag to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag.

Keilman teaches the drain bag constructed of flexible plastic material (Col. 2, ln. 19, 20) and, consequently, fully capable of being folded in the claimed manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the steps of folding the drain bag to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag, as taught by Keilman in order to make the package portable.

47. In Re claim 33, Dadson in view of Lee disclose the claimed invention, but do not expressly disclose the method including the step of applying the drain bag on the solution bag.

Keilman teaches the system, wherein the drain bag is applied on the solution bag (See Col. 2, ln. 3, 10-13; Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the step of applying the drain bag on the solution bag, as taught by Keilman in order to form the package in such a manner to substantially reduce packaging size requirements and to simplify the packaging procedure.

48. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885), as applied to claim 12 above, and further in view of Maasola (US 4,772,497).

Dadson in view of Lee disclose the claimed invention discussed above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is manufactured of a plastic material having higher resistance against heat than PVC.

Maasola teaches the bag for medical solutions made of a mixture of polyolefin and an elastomer (See Abstract, ln. 9-12). Since the bag material of Maasola is substantially identical to the bag material of claim 14 by its chemical composition (See Specification, page 4, [0034], ln. 27-30), the resistance against heat is inherent, as per In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the drain bag manufactured of a

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plastic material having higher resistance against heat than PVC, as taught by Lee in order to make the bag compatible with the steam sterilization process.

49. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885), as applied to claim 27 above, and further in view of Shang et al. (US 2002/0115795).

Dadson in view of Lee disclose the claimed invention discussed above, but do not expressly disclose the method including the step of exposing the package for autoclave sterilization.

Shang teaches the step of placing (exposing) the tube set in a steam autoclave.

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of the autoclave sterilization process. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the step of placing (exposing) the tube set in a steam autoclave, of Shang in order to provide the method with the sterilization process known in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Ilya Y Treyger/

Examiner, Art Unit 3761

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767